

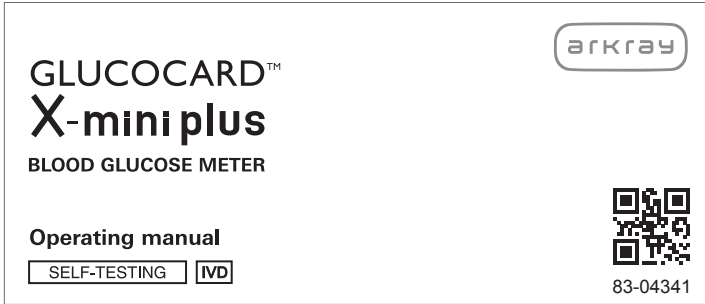
## Chapter 10 Technical Information

### 10.1 Specifications

Product	GLUCOCARD™ X-mini plus
Model	GT-1960
Test item	Blood glucose level
Sample	Fresh capillary whole blood**
Sample size	0.3 µL
Test strips	GLUCOCARD™ X premium Test Strips
Unit of measure	mmol/L
Test range	0.6 to 33.3 mmol/L
Test time	5 seconds from blood detection
Temperature compensation	Automatic compensation using built-in thermo sensor
Battery	3 V lithium battery (CR2032) × 2
Battery life	Approx. 1,000 tests (Actual number of tests may be less under some conditions of use.)
Power consumption	0.02 W (Max.)
Memory capacity	500 test results
Clock accuracy	Within ±75 seconds/month
Operating environment	Temperature: 10 to 40°C (50 to 104°F) Humidity: 20 to 80% RH (No condensation)
Expected life	3 years (according to company data)
Dimensions	L102 × W33 × 18.5 mm (L4.0 × W1.3 × 0.7 inches)
Weight	Approx. 46 g (1.49 ounces)

\*\* : Although whole blood samples are used for measurement, displayed results are equivalent to plasma glucose levels.

- Store the meter at 0 to 50°C (32 to 122°F).
- The meter is shipped with the batteries loaded. So, you can start testing immediately. However, the batteries may not satisfy the "Battery life".
- Product specifications and appearance are subject to change without notice.



Thank you for choosing the GLUCOCARD™ X-mini plus.  
We have designed this compact blood glucose meter for faster and easier testing of your blood glucose. We hope our product will help you manage your diabetes. This manual explains how to use your new meter. Before testing, carefully read through this manual and the package inserts that come with the GLUCOCARD™ X premium Test Strips and GLUCOCARD™ X-METER CONTROL. Pay particular attention to listed warnings and cautions. Please keep this manual handy for future reference. If you have any questions, please contact our authorized distributor(s) at the end of this manual.

## Chapter 1 Introduction

### 1.1 Intended Use

Your GLUCOCARD™ X-mini plus and GLUCOCARD™ X premium Test Strips are for quantitatively measuring the glucose level in fresh capillary whole blood. They are intended for use outside of the body (*in vitro* diagnostic use) at home or in a clinical setting as an aid to monitor and control blood glucose levels. **Do not use them to diagnose diabetes.** Also, **do not** alter treatment based on the test results of this meter without instructions from your doctor or healthcare professional.

### 1.2 Measurement Principle

Glucose in the blood reacts with the reagent in the test strip and this produces a small electric current. The strength of this current is proportional to the concentration of glucose in the blood. The meter measures this current and calculates your glucose level.


### 1.3 What's Included

- GLUCOCARD™ X-mini plus
- Carrying case
- Operating Manual (this manual)
- Simplified Manual / Information for Users
- Multilet™ (lancets)\*
- Multi-Lancet Device™ (lancing device)\*
- GLUCOCARD™ X premium Test Strips\*

Some kits do not include the above items with an asterisk (\*).

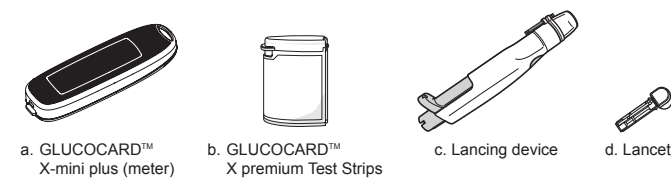
## Chapter 2 Before Tests


### 2.1 Important Health-Related Information

 **WARNING**

**Do not** use this meter for your blood glucose testing if you are being tested for galactose tolerance or xylose absorption. You may use this meter if you are taking PAM (1-Methylpyridine-6-carbaldehyde oxime).  
**These treatments may produce higher test results than your actual blood glucose level.** Taking unnecessary measures to lower your blood glucose level may induce severe low glucose symptoms such as coma.


### 2.2 What You Need for Each Test



 **WARNING**


Keep the meter, test strips and other items away from young children. Small items are choking hazards.

### 2.3 Cautions on Using the Meter

 **CAUTION**

- For accurate test results, allow the meter to adjust to the surroundings:  
Temperature: 10 to 40°C (50 to 104°F)  
Humidity: 20 to 80% RH (Relative Humidity)  
for 30 minutes before testing your blood glucose.
- **Do not** store or use the meter where:
  - There are sharp temperature fluctuations.
  - Humidity is high enough to cause condensation (bathrooms, drying rooms, kitchen, etc.).
  - There is a strong electromagnetic field (microwave oven, cell phone, etc.).
- **Do not** use the meter after it has been dropped in liquid or liquids have entered inside, even if dried afterwards.
- Keep hands away from the test strip slot on the meter. A thermo sensor is housed inside the meter to minimize detection of errors.
- **Do not** connect the communication cable to the connection terminal during testing. The meter may be damaged, leading to inaccurate test results.
- **Do not** apply blood directly to the test strip slot on the meter.
- **Do not** share your meter with anyone to avoid the risk of infection.

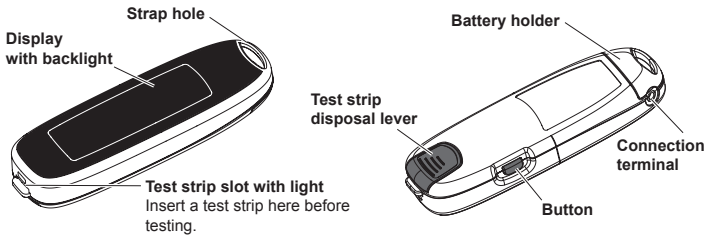
### 2.4 Cautions on Using the Test Strips

 **CAUTION**

- Use only the GLUCOCARD™ X premium Test Strips for testing with the GLUCOCARD™ X-mini plus. **Do not** use other test strips as it causes inaccurate test results.
- **Do not** use test strips beyond their expiration date. The expiration date is written on the test strip bottle next to "Exp.".
- For accurate test results, allow test strips to adjust to the surroundings:  
Temperature: 10 to 40°C (50 to 104°F)  
Humidity: 20 to 80% RH  
for 20 minutes before testing your blood glucose.
- **Do not** use the test strips if 6 months or more have passed since opening the bottle.
- The test strips are for single-use only. **Do not** use test strips that have already absorbed blood or control solution.

**NOTE**  
Store test strips in their original bottle to maintain quality. **Do not** transfer them to other containers.

### 2.5 Meter Parts



 IVD Directive (98 / 79 / EC)  
0 1 2 3

 MD Directive (93 / 42 / EEC)  
0 1 2 3

 MD Directive (93 / 42 / EEC)

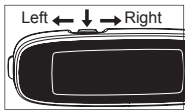
Manufacturer  
**ARKRAY Factory, Inc.**  
1480 Koji, Konan-cho, Koka-shi,  
Shiga, Japan

European Representative  
 **ARKRAY Europe, B.V.**  
Prof. J.H. Bavincklaan 5 1183 AT  
Amstelveen, the Netherlands

REV. 2011.09

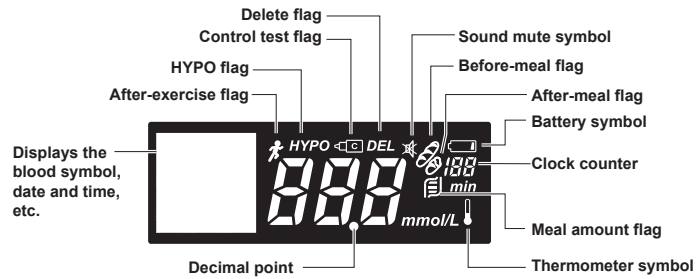
### Button Operations

This manual uses the following graphic icons to show you how to operate the button.



	Press the button once.
Twice	Press the button the specified number of times.
	Slide the button to the <i>right</i> .
	Slide the button to the <i>left</i> .
Hold	Hold the button in the direction of the arrow until the option you want appears on the screen.
Hold for 5 seconds	Hold the button in the direction of the arrow for the specified duration of time.

### 2.6 Display



### 2.7 Inserting Test Strips into the Meter

Start with the following steps to test your blood glucose level.

1. **With clean, dry hands, remove 1 test strip from the bottle.**  
**Do not** bend the test strip.

#### NOTE

- Tightly close the bottle immediately after taking out a test strip.
- **Do not** apply blood to the test strip before inserting it into the meter.

2. **Insert the test strip fully into the test strip slot.**

The meter turns on. Check that a full display appears as in chapter 2.6.

After the most recent test result appears, the blood symbol will flash on the screen.

If nothing appears on the screen, remove the test strip and insert it back into the test strip slot.

#### NOTE

- You can turn on the test strip light.
- The test result that appears right after power turns on is the most recent result without a control test flag or delete flag.
- If the thermometer symbol appears on the screen, see "If a Message Appears" in the "Information for Users".
- If you insert a test strip beyond the expiration date you set, the blood symbol and expiration symbol will alternately flash on the screen. If this occurs, see chapter 6.3.

#### CAUTION

If you cannot test your blood glucose due to a problem with your meter or test strips, promptly contact your healthcare professional and distributor.

3. **To flag the test result:**

See step 2 in chapter 5.1.

#### Next ...

Go to chapter 3 "Blood Sampling". Draw blood and apply it to the test strip no more than 5 minutes after you insert the test strip into the meter. Double beeps begin to sound 4 minutes and 30 seconds after inserting the test strip. Thirty seconds later, the meter turns itself off.

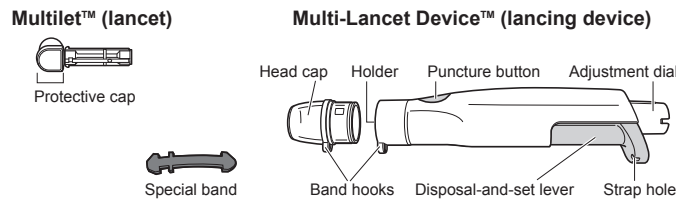
#### NOTE

In the ECO mode, the blood symbol flashes 2 minutes shorter than otherwise. See chapter 7 "Meter Setup".

## Chapter 3 Blood Sampling

This chapter briefly explains how to get a blood sample using the Multi-Lancet Device™ and Multilet™. If using some other lancing device to sample blood, see the manual for that device.

### 3.1 Lancing Device Parts



### 3.2 Cautions on Using the Multi-Lancet Device™

Follow these cautions to reduce the risk of infection by pathogenic microorganisms.

#### CAUTION

- Wash the puncture site with soap and water. Dry the site thoroughly before sampling blood.
- **Do not** share the same lancet or lancing device with anyone to avoid the risk of infection.
- Always use a new lancet. Lancets are for single-use only. **Do not** reuse a lancet that you have already used.

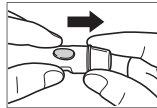
### 3.3 Selecting a Sampling Site

**Alternative site testing (AST):** This meter can test the glucose level of blood from your fingertip, palm, forearm or upper arm. However, test results from sites other than the fingertip may differ from a fingertip measurement. Consult your doctor or healthcare professional before testing blood from the palm, forearm or upper arm.

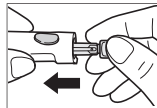
Use blood from:	If you are going to test:
Fingertip, palm, forearm or upper arm	<ul style="list-style-type: none"><li>■ Before meals</li><li>■ Two hours or more after meals</li><li>■ Two hours or more after exercise</li></ul>
Fingertip	<ul style="list-style-type: none"><li>■ When there is the possibility of blood glucose level changing rapidly (e.g. after meals or exercise)</li><li>■ When experiencing symptoms of hypoglycemia such as perspiration, cold sweats, a floating sensation or trembling</li><li>■ When immediate testing is needed for suspected hypoglycemia</li><li>■ When in poor physical condition such as having a cold, etc.</li></ul>

### 3.4 Sampling from Your Fingertip

1. Remove the head cap.



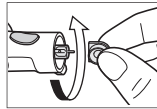
2. Insert a new lancet into the holder until it stops.



#### NOTE

Use a lancet before its expiration date.

3. Twist off the protective cap on the lancet. Keep the protective cap for disposing of the lancet after the test.



## Chapter 8 Control Test

This meter checks itself every time you insert a test strip. You do not need to run frequent control tests. Do a control test if:

- You suspect the meter or test strips are not working properly.
- You dropped the meter.
- You damaged the meter.
- Your test results do not match how you feel.
- You want to check performance of the meter and test strips before a blood glucose test.

#### NOTE

Use only the control solution, GLUCOCARD™ X-METER CONTROL, to test your meter and test strips

#### CAUTION

- **Do not** use control solutions beyond their expiration date. The expiration date is written on the control solution bottles next to "Exp.".
- Leave the meter and test strips at 10 to 40°C (50 to 104°F) and 20 to 80% RH, and the control solution at 22 to 28°C (72 to 82°F) for at least 30 minutes before running the control test.
- **Do not** drink control solution. It is not for human consumption.
- Keep control solution away from skin and eyes. Contact may cause inflammation.

1. See steps 1 and 2 in chapter 2.7.

2. **Select the control test flag.**

As an alternative, you can attach the control test flag after the test result appears on the screen. Test results with the control test flag are not part of your result averages.

3. **Make sure that the blood symbol is flashing on the screen.**

4. **Squeeze a drop of control solution to the tip of the test strip.**

The test will not start if you apply your control solution to the check window directly.

The test starts when the meter detects the control solution. The meter counts down from 5 to 1 during the test.

#### NOTE

- Tightly close the control solution bottle.
- **Do not** touch the test strip once the meter starts counting down.

5. **Check your test result is within the acceptable range.**

The acceptable range is shown on the package insert that come with the control solution. If within range, the meter and the test strip are working properly. If out of range, test the control solution again.

#### CAUTION

If you still have test results that are out of the acceptable range, stop using your meter, test strips and control solutions, and contact your distributor.

6. **Slide the test strip disposal lever to eject the test strip.**

The meter turns itself off.

## Chapter 9 Meter Care

### 9.1 Storing Your Meter

After use, tightly close the caps of the test strip bottle and control solution bottle to maintain their quality.

Store your meter, test strips, control solutions and manuals in your carrying case and store it in a dry location. The correct storage temperature is 0 to 50°C (32 to 122°F) for the meter and 1 to 30°C (34 to 86°F) for the test strips and control solutions. **Do not** freeze. Avoid heat, humidity and direct sunlight.

#### CAUTION

To obtain accurate test results:

- **Do not** use test strips or control solutions if their bottles are broken or have been left open.
- **Do not** use the test strips or control solutions beyond their expiration dates.

### 9.2 Cleaning Your Meter and Lancing Device

Your meter and lancing device do not need special cleaning. If your meter and lancing device get dirty, wipe them with a soft piece of cloth moistened with water. To disinfect these items after cleaning, wipe with a soft cloth moistened with 70% ethanol, 70% isopropanol or diluted household bleach (0.05% sodium hypochlorite solution).

### 9.3 Changing the Batteries

When the battery symbol appears on the screen, the batteries are getting low. Before using your meter, change the batteries. Past results remain in the memory even when the batteries are changed.

#### NOTE

Your meter uses two CR2032 3V lithium batteries. This type of batteries is available in many stores. Keep spare batteries handy at all times.

You do not need to set the date and time if you insert new batteries within 1 minute after removing the old batteries. Even if you change the batteries within 1 minute, your meter's clock may stop if:

- The batteries are not replaced soon after the battery symbol appears.
- The batteries are inserted upside down.
- You touch the metal parts inside the meter with hands or metal.

1. Make sure the meter is off.

2. Grip the strap hole with the tip of your finger and pull open.

3. Remove the batteries.

4. Set the new batteries into the battery holder with the "+" side facing upward.

#### NOTE

If the batteries are inserted upside down, the meter will not operate.

5. Close the battery holder.

6. The "SET" screen appears when the time has been reset. If it appears, set the correct time. See the setup mode flowchart in chapter 7. If you do not set the time, all subsequent test results will be stored as 12:00 AM or 00:00.

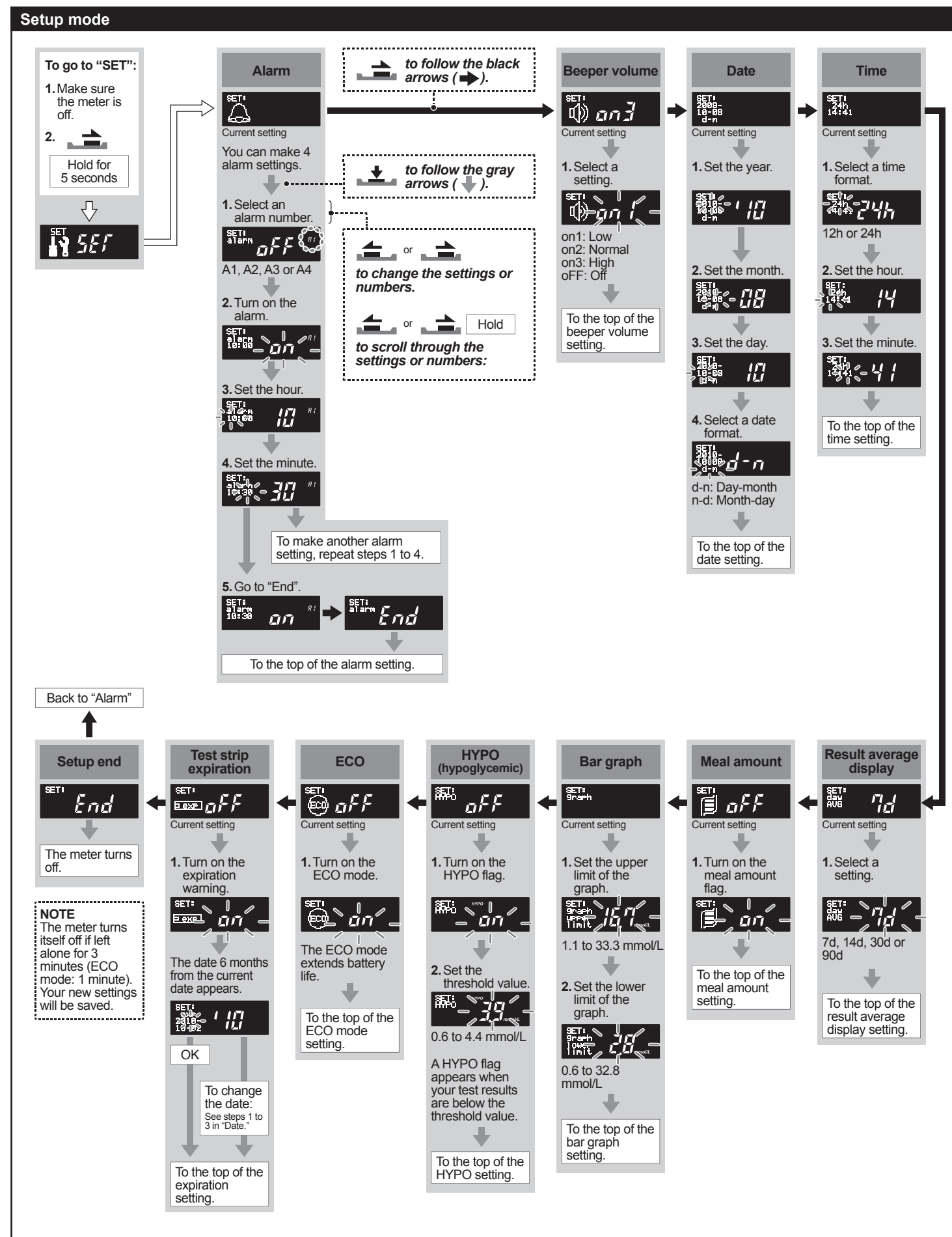
Dispose of old batteries according to your local environmental regulations.



## Chapter 7 Meter Setup

Your meter is set up as below at the time of purchase. To change the settings, see the setup mode flowchart.

- Alarm: Off
- Result average display: 7d
- ECO: Off
- Beeper volume: High (3)
- Meal amount: Off
- Test strip expiration: Off
- Date: Current local time
- Bar graph: Upper limit 16.7 mmol/L, Lower limit 2.8 mmol/L
- Time: Current local time
- HYPO: Off



4. Attach the head cap to the lancing device body.

5. If needed, adjust the lancing depth by turning the adjustment dial.

6. Wash the puncture site with soap and water. Dry thoroughly.

7. Press the head cap against your fingertip and press the puncture button lightly.

If you accidentally press the puncture button before reaching the puncture site, press the disposal-and-set lever until you hear a click. The device is then reset.

8. Obtain as much blood as that shown in "Actual size" on the right.

**Next ...**  
Go to chapter 4 "Testing Your Blood Glucose".

### 3.5 Sampling from Your Palm, Forearm or Upper Arm

1. See steps 1 to 5 in chapter 3.4.

2. Select a soft, fleshy area on the palm, forearm or upper arm that is free of visible veins, moles and hair and away from bone.

3. Massage the puncture site.

4. Wash the puncture site with soap and water. Dry thoroughly.

5. Press the head cap hard against the puncture site for about 10 seconds. Press the puncture button lightly.

If you accidentally press the puncture button before reaching the puncture site, press the disposal-and-set lever until you hear a click. The device is then reset.

6. Hold the head cap against the site. Add and reduce pressure to the site repeatedly, one cycle per second, to obtain as much blood as that shown in "Actual size" on the right.

If you obtained an insufficient amount of blood, rub or warm a new puncture site to increase blood flow. Then, make another puncture.

**Next ...**  
Go to chapter 4 "Testing Your Blood Glucose".

## Chapter 4 Testing Your Blood Glucose

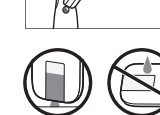
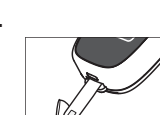
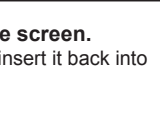
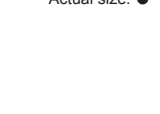
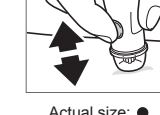
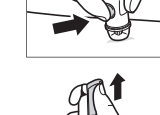
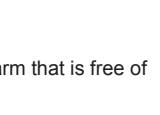
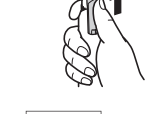
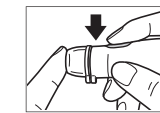
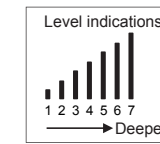
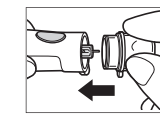
**1. Make sure that the blood symbol is flashing on the screen.**

If nothing appears on the screen, remove the test strip and insert it back into the slot. Then, wait until the blood symbol starts flashing.

**2. Touch the tip of the test strip to the drop of blood.**

Let the test strip draw up blood until the dark-colored check window is filled with blood.

Accurate test results will not be obtained if you apply your blood to the check window directly.



When you hear a beep, remove the test strip from the blood. The test starts when the meter detects enough amount of blood. The meter counts down from 5 to 1 during the test.

### NOTE

- For accurate test results, touch the test strip to your blood in less than 20 seconds after puncturing.
- **Do not** test blood that runs or spreads out from the puncture site.
- **Do not** smear blood on the test strip.
- **Do not** press the test strip into your puncture site with force.
- If the meter does not start counting down, touch the test strip to the drop of blood again within 10 seconds. Use a new test strip if more than 10 seconds have passed.
- Keep your hands away from the test strip once the meter starts counting down.

### 3. Read your test result.

You will hear a beep when the test result appears on the screen. The meter stores this test result and the test date in the memory.



### Bar graph

#### Test results

The 6 most recent test results appear as a bar graph, with the newest result at the far right.



To switch the bar graph to the current date and time:

### WARNING

Test results are shown in mmol/L. You cannot change the unit of measure. If the results appear in mg/dL by any possibility, contact your distributor immediately. Using mg/dL may cause you to misread test results and lead to incorrect treatment.

### CAUTION

#### ■ If "Lo" or "Hi" appears on the screen:

Repeat the test. If "Lo" or "Hi" still appears, contact your doctor or healthcare professional. "Lo" appears if your test result is less than 0.6 mmol/L. "Hi" appears if your test result is more than 33.3 mmol/L.

#### ■ If test results do not match how you feel:

Make sure you performed the test properly as explained in chapters 2 to 4. Then, do a control test to check there are no problems with the meter or test strips. If you tested blood from the palm, forearm or upper arm, repeat the test with blood sample from a fingertip. If test results still do not match how you feel, contact your doctor or healthcare professional.

■ **Do not** ignore test results. **Do not** alter your blood glucose management or treatment without consulting your doctor or healthcare professional. It is important to follow their instructions.

### NOTE

In the ECO mode, the test result appears on the screen 2 minutes shorter than otherwise. See chapter 7 "Meter Setup".

### 4. Slide the test strip disposal lever to eject the test strip.

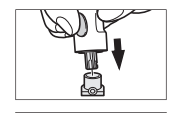
The meter turns itself off.

### CAUTION

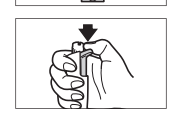
Point your meter down and away from others when ejecting the used test strip.

### 5. Remove the used lancet from your lancing device.

Remove the head cap from the lancing device body. Stab the protective cap with the tip of the lancet.



Push the disposal-and-set lever in the direction of the arrow to remove the lancet.



### Disposal of Biohazardous Waste

Test strips and lancets qualify as biohazardous waste once used to test blood glucose. After use, dispose of them according to your local regulations on biohazardous waste.




## Chapter 5 Managing Your Test Results


### 5.1 Flagging Test Results


Flags help you categorize and identify results.


1. Leave the test strip in the meter after the test result appears on the screen.


2. Select the flag you want.


**Control test flag**  
Control test results. Not part of your result averages.




**Delete flag**  
For inaccurate results. Not part of your result averages. The delete flag can be attached only after testing.


**Before-meal flag**  
For results obtained before eating

**After-meal flag**  
For results obtained after eating

**Clock counter**  
If the clock counter setting is on, the elapsed time appears on the right of the after-meal flag. See chapter 6.2.

**Meal amount flag**  
When the meal amount setting is on, the meal amount flag appears below the after-meal flag. Select the amount of food you ate from the 3 levels shown on the left.

  
50%  
  
80%  
  
Full

**After-exercise flag**  
For results obtained after exercise

3. Slide the test strip disposal lever to eject the test strip. The meter turns itself off.

### 5.2 Reviewing Past Results

You can review past results stored in the memory. Your meter stores up to 500 test results. New results beyond the 500th overwrite previously stored results in the order of oldest first.

1. Make sure the meter is off.

2. Turn on the meter.

The most recent test result appears on the screen.

The 3-digit number following "M:" is the order in which test results are stored, with the most recent result first. The screen also shows the date and time when the test was done.

3. View the test result you want.

To go to the next result:



To go back to the previous result:



To scroll through results:



Hold

4. To turn off the meter:



Twice

### 5.3 Viewing Result Averages

You can view result averages for the set interval (7, 14, 30 or 90 days).

1. See steps 1 and 2 in chapter 5.2.

2. View the averages of your glucose test results.



3. To view the averages with a flag:



The number of tests included in the calculation of the result average.



4. To turn off the meter:



### 5.4 Deleting All Test Results from the Memory

You can delete all test results from the memory. Remember that results cannot be retrieved once deleted.

1. See steps 1 and 2 in chapter 5.2.

2. Go to the "AVG (average)" screen.



3. Go to the "ALL CLEAR" screen.



Hold for 5 seconds



4. Select "YES".



5. Delete the test results from the memory.



Hold for 2 seconds



The meter then turns itself off.

## Chapter 6 Useful Functions for Your Test

### 6.1 Using the Alarm

The alarm reminds you when to test your blood glucose. You can set the alarm to sound at 4 different times in a day.

#### Setting the Alarm

See chapter 7 "Meter Setup."

#### When the Alarm Reaches the Set Time

A series of short beeps sound for 1 minute.



To stop the alarm:



### 6.2 Using the Clock Counter

You can store after-meal results together with the time elapsed since the beginning of your last meal (up to 180 minutes).

#### Before Your Meal: Starting the Clock Counter

1. Make sure the meter is off.

2. Go to the "DATE:" screen.



3. From the "DATE:" screen, go to the "Meal Time" screen.



Hold for 2 seconds



4. Turn on the clock counter.



5. When you are about to start your meal, go to step 6 with "0 min" flashing.

If you forgot to start the clock counter, select the time elapsed since the beginning of your last meal in 15-minute blocks.



6. Start the clock counter.



After the current date and time appear, the meter turns itself off.

To view the elapsed time while the meter is off:



#### Testing after Your Meal: Changing the Elapsed Time

1. After eating, test your blood glucose.

When the clock counter setting is on, the elapsed time and after-meal flag appear on the right of the test result.



2. To change (or set) the elapsed time:



Hold for 2 seconds



Select the time.



or



Confirm your setting.



3. Slide the test strip disposal lever to eject the test strip.

The meter turns itself off and the test result is stored together with the elapsed time.

### Stopping the Clock Counter

1. Repeat steps 1 to 3 in "Before Your Meal: Starting the Clock Counter".

2. Select "no".



3. Confirm your selection.



### 6.3 Managing the Expiration Date of Test Strips

You can set the expiration date of test strips. The expiration warning then appears if you insert a test strip into the meter after the set date.

#### Setting the Expiration Date of Your Test Strips

Select the earlier date of the following:

- Six months from opening the test strip bottle
- Date next to "Exp." on the test strip bottle

To set the expiration date, see chapter 7 "Meter Setup".

#### Checking the Set Expiration Date

1. Make sure the meter is off.

2. View the expiration date.



The expiration date appears after the current date and time.

#### Expiration Date Reminder

**Do not** use the inserted test strip and other test strips in the same bottle, if the blood symbol and expiration symbol alternately flash on the screen.

